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(54) **Pharmaceutical product container with two separate substances and a mixing device and dosed dispensation.**

(57) Of the type that permit the mixing of two products located in two containers (1 and 5, 5'). In the inside of the top container (5, 5'), there is a tubular sleeve (13) with a wing terminated by a truncated-cone shaped portion (15) like a medicine dropper, and with a bevel-edged bottom edge (17) to cut the bottom of the vessel (5), upon screwing down the cap (18) after removing a safety seal (19.) The container (5, 5') extends into a neck (8.) It is characterized in that the mouth of the neck (8) has an annular recess (22) and a discoidal wing (14) provided with a bevel (26) that is retained in the annular recess (22) upon the bottom of the container (5) breaking, preventing the removal of the tubular sleeve (13), the latter containing a pointed longitudinal appendix (24) to break the tearable bottom (6) without making any additional effort. Diametrically opposite the appendix (24) there is a longitudinal recess (27) that prevents the complete cutting of the perimeter of the bottom (6) which remains connected to the top container (5) by a small piece, preventing the falling of the bottom (7) to the bottom container (1.)

It has diverse seals and sealing rings. Its assembly is adaptable to the packaging process and conditioning chosen, permitting the selective and independent filling of the top part and bottom part as if there were

two separate containers.

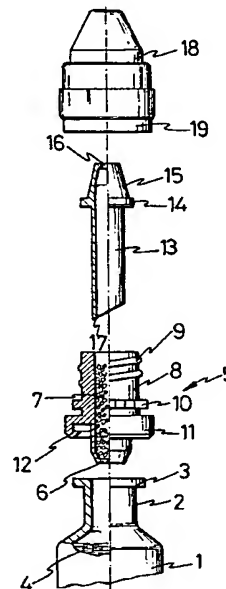


FIG. 1

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## OBJECT OF THE INVENTION

As is expressed in the title of this specification, the present invention consists of a pharmaceutical product container, with two separate substances and a mixing device and dose dispenser, of the type that permit the mixing of two different products, one of which is located inside the bottom container itself, while the other one is located inside a top container with a weakened tearable perimeter, upon the bevel edge of a tubular sleeve that terminates at the top in a discoidal wing from which it continues according to a truncated-cone shaped portion for use as a medicine dropper, pressing on the same, all upon screwing down a cap after removing a seal; and that has the purpose of pressing the bevel-edged edge of the tubular sleeve to allow partial cutting of the weakened perimeter of the bottom of the top container, this partial cut, causing total opening between both compartments, but preventing the falling of the tearable bottom, thus avoiding that the bottom moves freely around the inside of the bottom container, once it has been torn.

Another object of the invention consists of providing retaining means of the tubular sleeve over the top container, once the bottom thereof has been broken, causing the mixing of the two products and permitting that upon applying the mixture, by pressing on the bottom container or else by incorrect handling of the container, the removal of the tubular sleeve cannot take place, a situation in which the product contained in the bottom container would come out, which would determine incorrect application of the mixed product. For the same purposes the seal between the bottom container and the top container has been designed.

The invention also considers a group of rings and seals that are characterized in maintaining the sealing and invulnerability of the container, both before removal of the seal, maintaining these two features in the components separate, as well as after having broken the seal and having carried out the mixing of the two components, maintaining the final sealing and invulnerability of the inside of the container. Only the discharge of the mixture through the dosing medicine dropper is permitted.

The container permits a final filling and conditioning that is very diverse, permitting the varying of the order of filling the top part and the bottom part, which prevents crossed contamination, which is a typical problem in the pharmaceutical industry.

## BACKGROUND OF THE INVENTION

On the pharmaceutical market in general and especially in the dermic, ophthalmic, otic, oral and nasal sectors, there are multiple products, such as

certain eye drops, whose shelf life, once all of the ingredients have been mixed, in most cases do not exceed four weeks.

In view of such circumstances, for some time now the ingredients of the product have been grouped in two parts that are packaged separately and independently.

Generally, one of the parts is in a powdered lyophilized form, while the other one is in a liquid state. Each one of the parts maintains individually its stability during the proposed period of validity, the user himself being the one who must mix both parts when the product is to be administered. The stability of the reconstituted product suffices to guarantee the indicated time of use.

European patent no. 344.849 and European patent no. 210.425 provide solutions to this problem.

European patent no. 210.425 protects a device of this type, in which the mouth of the container has a thread upon which the cap provided with a seal is retained. Likewise, there is a cup pressed on the mouth, inside of which the tubular sleeve is housed which is terminated in its top edge by a discoidal wing as of which it continues according to a truncated-cone shaped portion to carry out the functions of a medicine dropper.

In this patent, after removing the seal from the cap, the same can be screwed down, the movement of which pushes the tubular sleeve, which presses against the bottom of the cup, carrying out the breaking thereof and producing the mixing of both products.

This patent presents the inconvenience that after removing the seal to effect the breaking of the bottom it is necessary to exert a certain effort; at the same time that in order to permit the application of the mixed product it is necessary to press the container, situation in which the discharge of the cup and/or of the tubular sleeve, thus, all of the product would come out, which is a serious inconvenience upon not applying the necessary amount of the product. Neither are seals shown, which prevents use for the mixing of two liquids, nor is the invulnerability of the container foreseen, nor a mechanism that permits the dose to be repeated (for examples, a drop.) Nor is the versatility of filling and final conditioning of the container set forth.

Concerning European patent no. 344,849 it protects a device of these characteristics, in which the cup has an outside flap placed coaxially that includes inside an annular rib whereby it is retained in the edge of the mouth of the container, in such a way that it prevents when application takes place, that the cup can be removed, characteristic which on the other hand is not necessary in this model given that it does not act as a medicine dropper,

since the application of the mixed product tends to be done entirely during treatment. In this patent, the breaking of the bottom is done by pressing the cap and not screwing it, as in the prior case, which may mean a difficulty for breaking the bottom of the cup given that the force to be exerted is much greater.

Besides, in the cited patent, the cylindric sleeve may be removed by effecting the application, which would likewise be an inconvenience.

### DESCRIPTION OF THE INVENTION

In order to solve the above cited inconveniences, the invention comprises a bottom container consisting of a bottle upon which another top container is placed, which has the particularity that after breaking the bottom of the latter, the tubular sleeve remains retained in the top container, which in turn is retained in the edge of the mouth of the bottom container, in such a way that it prevents upon applying the mixed product that removal can take place, either of the top container or of the tubular sleeve, or of both at the same time, permitting the application of the exact dosed amount of the mixed product. The invention has diverse projecting rings, labyrinth-type seals and embossments that ensure a good sealing of the entire device, before and after the breaking of the seal. Likewise, mishandling of the container is prevented, ensuring by means of seals the invulnerability of the same. Another advantage provided by the invention consists of the versatility involved in the filling stage, making it possible to carry out this stage in two separate containers, and in the desired order.

In order to establish these advantages, the top container of the invention is of the type that are comprised of a coaxial in which a retaining rib is included in the edge of the mouth of the bottom container, but with the particularity that said top container is also provided with a helicoidal thread to provide the the threading of the cap with a perimetric edge to establish the retention of the seal of the cap and of an annular recess in the mouth thereof.

Upon the inside of the top container, which is likewise done conventionally, there is a tubular sleeve whose top terminates in a discoidal wing, from which it continues according to a truncated-cone shaped portion, which can function as a medicine dropper (depending on whether or not it is of interest in the application,) but with the particularity that the discoidal wing, in one of the embodiments, advantageously offers a certain conicity, to define a bevel that is complemented with an annular recess provided in the mouth of the top container, establishing the retaining of the tubular sleeve in said

mouth.

Conventionally, the bottom edge of the tubular sleeve is bevel-edged, a solution which has been used in one of the embodiments, and which has been improved in the following embodiment, so that in the latter the bottom edge is horizontal and in it a longitudinal, continued decreasing cross sectioned appendix which facilitates partial breaking of the bottom of the top container is included, without this implying an additional effort. The breaking is only partial, given that there is a longitudinal recess in the side diametrically opposite the tearing appendix, this recess, which prevents the total breaking of the bottom of the top container makes said bottom remain joined to the top container, by a fine segment, which does not hamper the mixing, because it is flexible, but it does prevent the falling of the bottom of the top container inside the bottom container.

The bottom of the top container, which is also made conventionally, can have a perimetric weakening in the inside wall, with the particularity that the weakening can be included in the outside wall, or in both, for the purpose of providing better breaking, preventing particles due to a poor cutting from appearing. It also ensures the sealing of the top container, against migration which may exist through the walls of the bottom of the top container, giving a greater thickness to the center area of said bottom; given that the migration depends on the surface in contact and on the thickness of the same.

Therefore, by means of the invention and after removal of the seal from the cap, the same can be screwed down effecting the displacement of the tubular sleeve, which partially breaks the bottom of the top container without exerting additional effort and establishing a mutual axial retaining between the cup and the tubular sleeve, upon effecting the retaining on the peripheral edge of the discoidal wing, in the annular recess provided in the mouth of the top container, in such a way that it prevents, upon pressing on the bottom container to effect the required dosage, that removal of the top container and/or of the tubular sleeve can be produced.

Hereinafter to provide a better understanding of this specification and forming an integral part of the same, a series of figures in which the object of the invention has been represented with an illustrative and non-restrictive nature is attached hereto.

### BRIEF DESCRIPTION OF THE FIGURES

Figure 1.- It shows a partially sectioned and exploded view of the different elements that comprise a possible embodiment.

Figure 2.- It is a partially sectioned view of the elements already assembled and once the seal has

been broken, according to the embodiment in figure one.

Figure 3.- It is an exploded view of each and every one of the elements that comprise the invention, according to a second embodiment.

Figure 4.- It shows a view equivalent to that of figure 3, with the exception that the elements are sectioned, with the exception of the cap.

Figure 5.- It shows a sectioned view of the second embodiment, in which the elements are assembled and ready for use, without the bottom of the top container having been broken.

Figure 6.- It is a side view without sectioning the previous figure.

Figure 7.- It is a sectioned view equivalent to that of figure 5, but with the exception that after having removed the seal, the bottom of the top container has been broken upon screwing down the cap and having subsequently removed the cap.

Figure 8.- It is a raised view without sectioning the previous figure.

Figure 9.- It is a sectioned view of the top container.

#### DESCRIPTION OF ONE OR SEVERAL EMBODIMENTS OF THE INVENTION

Hereinafter a description is made of the invention based on the above cited figures.

In the first place a first embodiment, whose characteristics are improved in the second embodiment, is described.

Hence, in said first embodiment, referring to figures one and two the invention has a bottom container (1) in which one of the products (4) to be mixed is introduced.

The bottom container (1) has a neck (2) in whose mouth edge (3) has been provided for.

Upon the mouth of the bottom container (1) is a top container (5) that is provided with a small flap, which includes an annular rib (12) by means of which the retaining of the top container (5) on the edge (3) of the bottom container (1) is done.

The top container (5) has a tearable bottom (6), in such a way that introduction of a second product (7) that must be mixed with the one included in the bottom container (1) is permitted, thus the latter is separated from the former.

The top container (5) extends superiorly according to a neck (8) in which the helicoidal threads (9) that permit screwing of a cap (18) are included.

The neck (8) is provided with a perimetric projection (10) that constitutes a retaining means of the seal (19) of the cap (18.)

Inside the top container (5) a tubular sleeve (13) with a bevel-edged decreasing cross sectioned bottom edge (17) is introduced.

The top part of the tubular sleeve (13) is terminated according to a discoidal wing (14) that is terminated at the top according to a truncated-cone shaped portion (15) that acts as a medicine dropper.

The perimetric projection (10) has a plurality of sawteeth, which are complemented by another plurality of sawteeth provided in the seal (19) of the cap (18.)

In this way, it is possible to screw the cap (18) with its seal (19) until the latter contacts with the small flap the supports the annular rib (12) of the top container (5.) In this situation, the locking of the seal (19) in the perimetric projection (10) is produced by the action of the cited sawteeth, whereby upon screwing off the cap (18) said seal (19) of the cap (18) breaks making it possible to remove the seal. In this situation, upon screwing the cap (18) it comes in contact with the perimetric projection (10), with which in movement thereof the tubular sleeve (13) is pushed axially causing the partial cutting of the bottom (6) by the action of the bottom bevel edge (17), easily and without any additional effort.

Afterwards it is possible to mix the products (4 and 7), which are administered in a dosed manner upon pressing on the bottom container (1.)

In this embodiment there are some problems regarding the sealing and retaining of some elements with regards to others.

In order to solve these inconveniences, a second embodiment is described, wherein the perfect retaining between the different elements is established as well as a total sealing; just as it is indicated hereinafter.

In order to obtain these objectives, in the second embodiment, the top container (5) is provided with some transversally placed sealing rings (21) which are complemented with a sealing ring (25) provided close to the bottom edge of the tubular sleeve (13) in this way, upon introducing the tubular sleeve (13) in the inside of the top container (5'), total sealing between both containers is made possible.

Besides, in order to facilitate the breaking of the bottom (6) of the top container (5'), the bottom edge of the tubular sleeve (13) has a pointed decreasing cross section longitudinal appendix (24), diametrically opposite thereto is a longitudinal recess (27) that ensures that the total cutting of the perimeter of the bottom (6) of the top container (5') is prevented.

The discoidal wing (14) of the tubular sleeve (13) with its peripheral edge offers a certain concavity defining a bevel (26) that is complemented by an annular recess (22) provided in the mouth of the neck (8) of the top container (5') in such a way that upon screwing down the cap, after removing the

seal to break the bottom (6) just as it has been commented on in the first embodiment, the bevel (26) remains axially retained in the annular recess (22) placed in the mouth of the neck (8) of the top container (5'), producing the fastening between both elements in an effective manner.

In the top part of the neck (2) of the bottom container (1) a sealing ring (23) that permits sealing between the top container and the bottom container has been provided, once the annular rib (12) remains hooked in the edge (3) of the mouth of the bottom container (1), upon effecting the assembly on the same.

The truncated-cone shaped portion (15) that terminates at the top in a tubular sleeve (13), operates as a medicine dropper with controlled dosage, thanks to the inside coaxial cylinder (29.)

In the top end thereof the tubular sleeve (13) has a recess (28), that is complemented by an inside projection of the cap (18') to guarantee the sealing of the cap (18') with the tubular sleeve (13.)

Therefore the invention provides three levels of sealing and prevention mechanisms of improper use. The first level is established between the bottom container (1) and the top container (5), the second between the tubular sleeve (13) and the top container (5), and the third between the cap (18) and the tubular sleeve (13), by means of the above described elements.

The tearable bottom (6) of the top container (5) is very thick in its center part, for the purpose of reducing migration through said bottom (6), an inside perimetric weakening (30) and an outside perimetric weakening (31) having been provided for in order to prevent inadequate tearing, and the production of particles in the same.

The operating mechanism of this second embodiment is very similar to that described in the first embodiment, with the described improvements.

Besides, it should be indicated that in said second embodiment, an outside flap (20) is included and it half surrounds the neck (2) of the bottom container (1) that is presented as an extension of the bottom container (1), after effecting the assembly of the different elements.

Both embodiments permit the filling, with product (7), of the bottom container (1), in the first place, sealing it afterwards with the top container (5) or (5'), filled with product (4), closing the latter with the tubular sleeve (13) and finally screwing on the cap (18, 18').

Besides, it permits another possible solution which consists of effecting the filling, in the first place of the top container (5, 5'), with product (7), closing the latter with the tubular sleeve (13) screwing on the cap (18, 18'), and finally filling the

bottom container (1), with the product (4) sealing the entire device.

Another way to assemble the different elements consists of filling the top container (5, 5') closing it with the tubular sleeve (13), or filling the tubular sleeve (13) the cap (18, 18') previously embossed and the subsequent sealing of the top container (5, 5'). This versatility of filling permits the packaging of fluids with different viscosities, solids, which may be powder, lyophilized substances or pills.

### Claims

1. Pharmaceutical product container with two separate substances and a mixing device and dosed dispensation, of the type that permit the mixing of two different products, one of which is located inside a bottom container (1), while the other one is placed in a top container (5, 5') with a tearable bottom (6) provided with a perforated line to facilitate tearing thereof, the top container (5, 5') also having an outside flap (20) that half surrounds the neck (2) of the bottom container (1) and that includes inside an annular rib (12) by means of which the edge (3) of the mouth of the bottom container (1) is retained, there being in the inside of the top container (5, 5') with the possibility of movement, a tubular sleeve (13) provided with a bottom bevel edge (17) that permits partial cutting of the bottom (6) of the top container (5, 5'), upon screwing the cap (18, 18') on said top container (5, 5'), after removing a safety seal (19); and the top edge of the tubular sleeve (13) being terminated in a wing (14) after which there is a truncated-cone shaped portion (15) acting as a medicine dropper, allowing this function, thanks to an inside coaxial cylinder (29); essentially characterized in that the top container (5, 5') extends at the top according to a neck (8) that is provided with a helicoidal thread (9) of the cap (18, 18') and with a perimetric toothed projection (10) that is complemented by a set of teeth provided in the seal (19), both remaining locked in such a way that upon unscrewing the cap (18, 18'), the perforated line of the safety seal (19) breaks, withdrawing the seal and permitting the screwing of the cap to effect the breaking of the tearable bottom (6.)
2. Pharmaceutical product container with two separate substances and a mixing device and dosed dispensation, according to claim 1, characterized in that the beveled edge (17) of the tubular sleeve (13) has been replaced by a horizontal edge provided with a decreasing

cross section pointed longitudinal appendix (24), establishing a cutting element that permits breaking of the tearable bottom (6), without exerting any additional force; it being foreseen that diametrically opposite the longitudinal appendix (24), there is a longitudinal recess (27), that prevents complete perimetric breaking of the bottom (6); which remains connected by means of a weak connecting element that permits total rotation of the same in order to permit an entire mixture, and preventing the tearable bottom (6) from being able to fall inside the bottom container (1.)

3. Pharmaceutical product container with two separate substances and a mixing device and dosed dispensation, according to the above claims, characterized in that the discoidal wing (14) of the tubular sleeve (13) is provided with a peripheral edge with a certain conicity, to define a bevel (26) with regard to an annular recess (22) provided in the mouth of the top container (5'); all of this in order to effect the retaining of the bevel (26) in the annular recess (22) and therefore the retaining of the tubular sleeve (13) in the top container (5') upon the tearable bottom (6) breaking; all of this for the purpose of effecting the application of the mixed product, removal of the tubular sleeve (13) being prevented.

4. Pharmaceutical product container with two separate substances and a mixing device and dosed dispensation, according to the above claims, characterized in that the bottom container (1) has a sealing ring (23) that makes the seal with the outside wall of the top container (5'); sealing that is reinforced by an edge (3) of the mouth of the bottom container (1) upon sealing with said annular rib (12), it being provided for that the tubular sleeve (13) has close to its bottom edge a sealing ring (25) that is complemented with other sealing rings (21) provided in the inside of the top container (5') making the sealing possible between the tubular sleeve (13) and the top container (5'); once the mixing has taken place, the anchoring between the annular recess (22) of the top container (5') and the bevel (26) of the tubular sleeve (13) contribute to reinforcing the airtightness; and with the particularity that the tubular sleeve (13) has on top an inside recess (28) that is complemented with an inside projection of the cap (18) permitting the sealing between both.

5. Pharmaceutical product container with two separate substances and a mixing device and

dosed dispensation, according to the above claims, characterized in that the bottom container (1), is subject to being filled with product (4), in the first place, and subsequently sealing it with the top container (5, 5'), sealing the latter with the tubular sleeve (13), and finally screwing the cap (18, 18'); it being provided for that the top container (5, 5') is subject to being filled in the first place, sealing the latter by the tubular sleeve (13), screwing the cap (18, 18') and finally filling the bottom container (1), and sealing the entire device; and with the particularity that the filling of the top container (5, 5') is subject to being done, by filling the tubular sleeve (13), after screwing the cap (18, 18') and subsequently sealing with the top container (5, 5'); this all in order to establish a versatility of filling that permits the packaging of fluids with different viscosities, solids, which may be powders, granulates, lyophilized substances or tablets.

6. Pharmaceutical product container with two separate substances and a mixing device and dosed dispensation, according to the above claims, characterized in that the tearable bottom (6) of the top container (5, 5') is very thick in its center part, for the purpose of reducing migration through said bottom (6), an inside perimetric weakening (30) and/or an outside perimetric weakening (31) being provided for; to prevent inadequate tearing and the production of particles in the same.

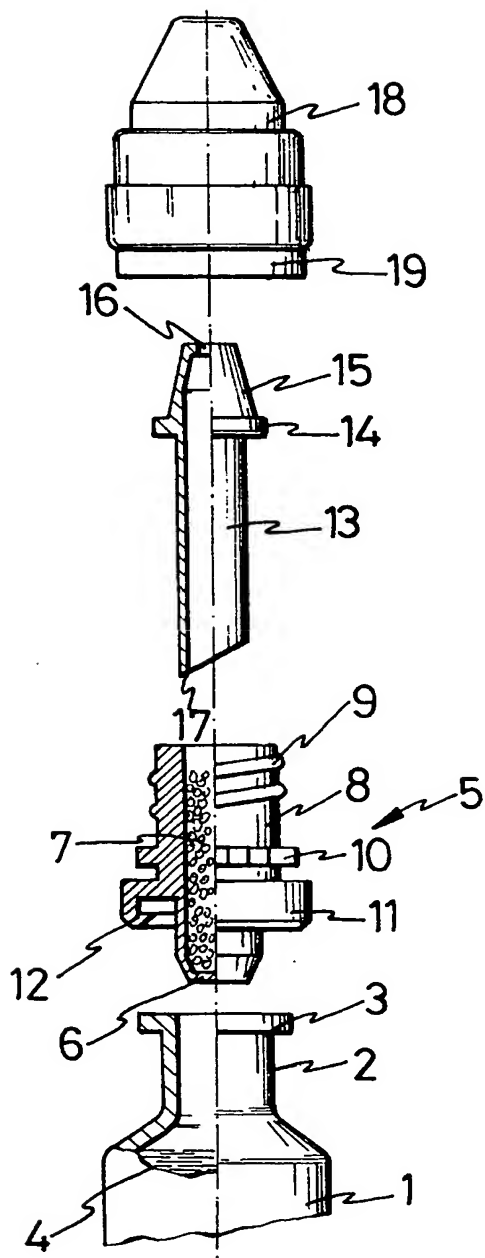


FIG. 1

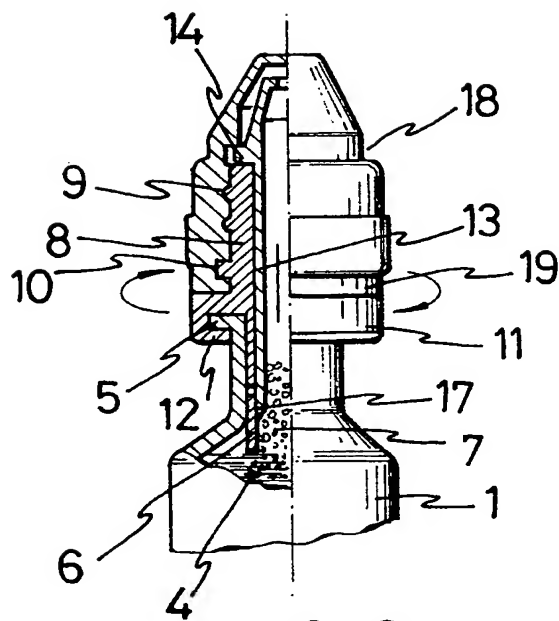


FIG. 2

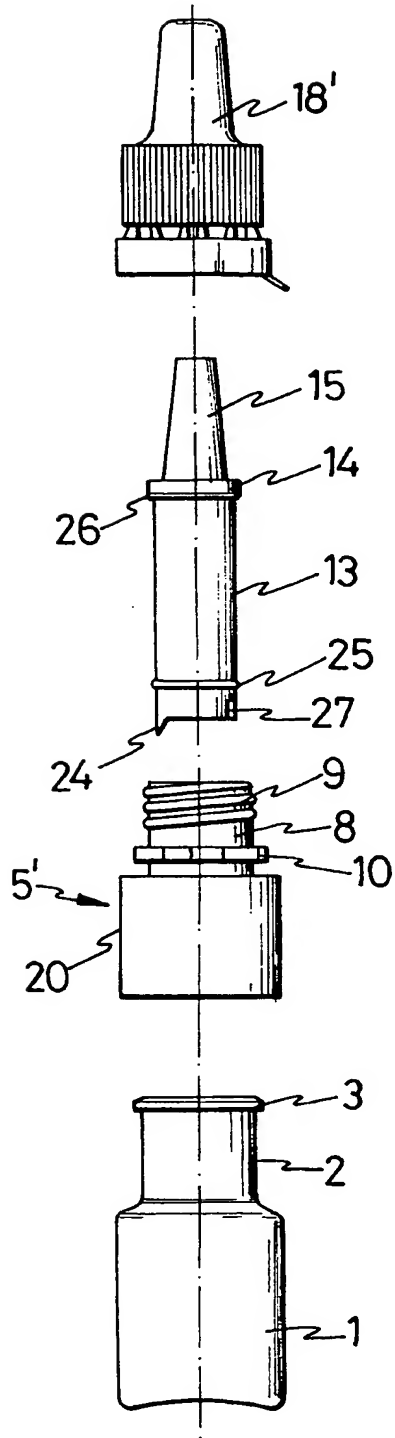


FIG. 3

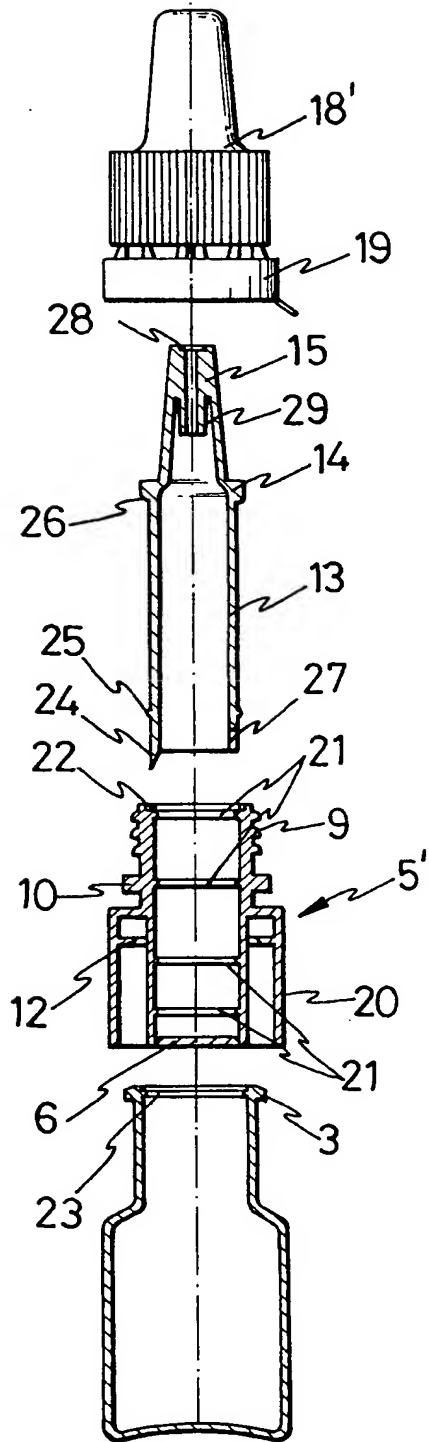


FIG. 4



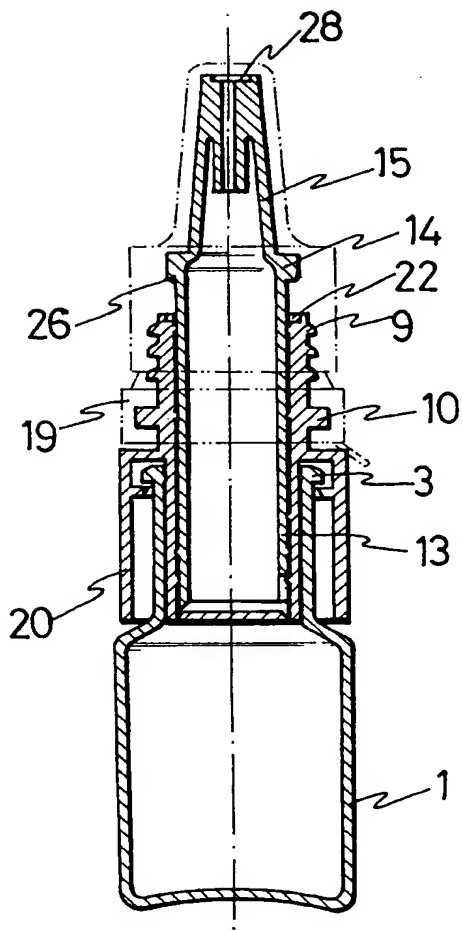


FIG. 5

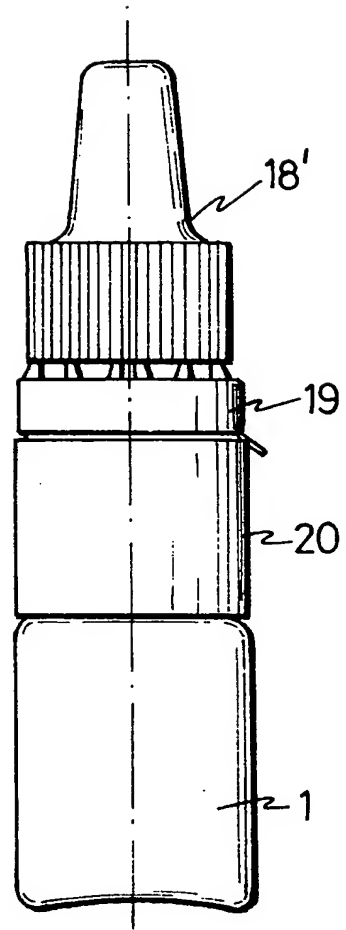


FIG. 6

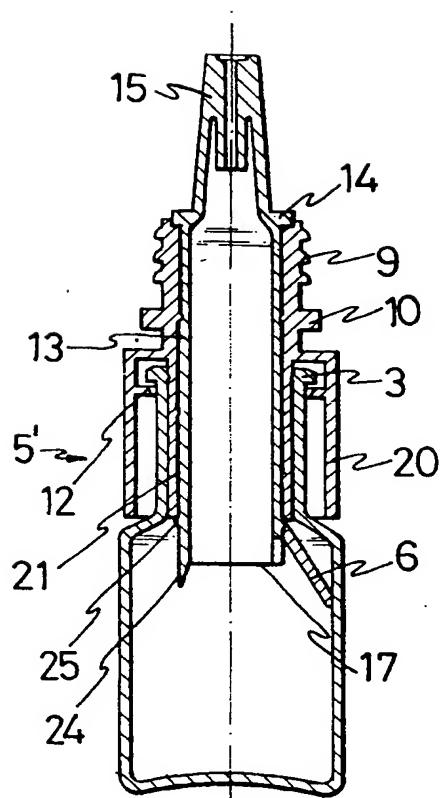


FIG. 7

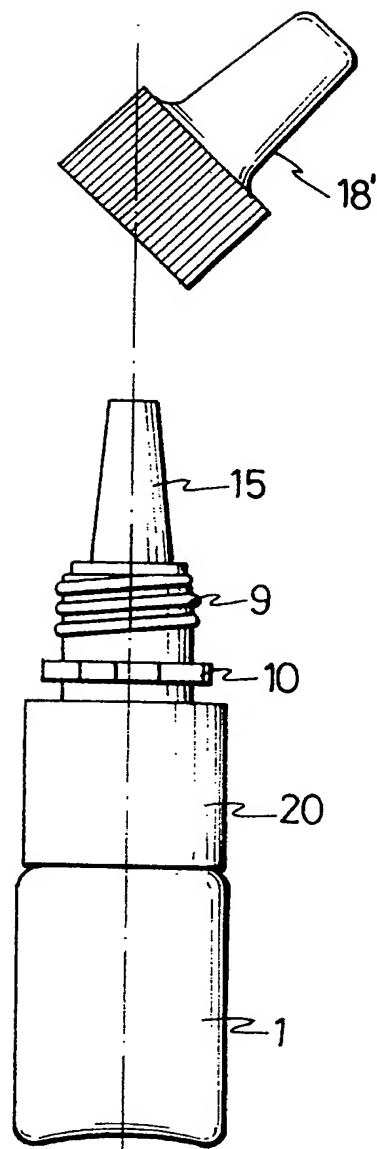


FIG. 8

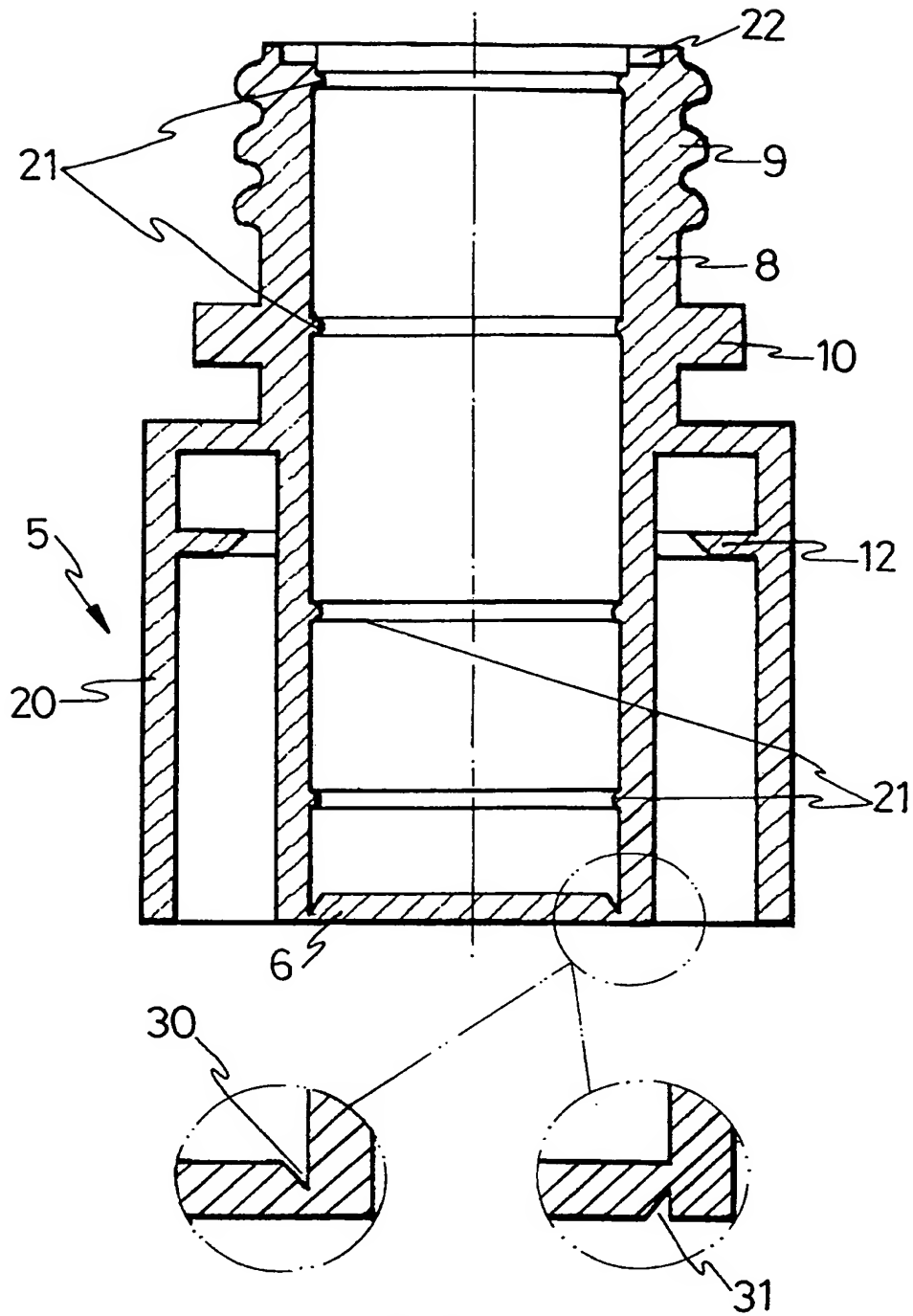


FIG. 9



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## EUROPEAN SEARCH REPORT

Application Number

EP 93 20 1827

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	FR-A-1 568 362 (LE NARDOU) * page 2, line 1 - page 3, line 20; figures 1-3 *	1,2,5	B65D51/28
A	FR-A-2 170 772 (INGE) * page 8, line 1 - page 9, line 14; figures 7-10 *	1,2,5,6	
A	US-A-3 802 604 (MORANE) * column 3, line 36 - column 4, line 18; figures 1,2 *	1,2,5	
D,A	EP-A-0 344 849 (MUTTERLE) * column 2, line 45 - column 3, line 39; figures 1,2 *	1,2,5	
E	EP-A-0 561 322 (FABBRI) * column 2, line 57 - column 3, line 51; figures 1-11 *	1-6	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			B65D A61J
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 13 OCTOBER 1993	Examiner VANTOMME M.A.
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